

Applicant's undersigned representative appreciates the courtesy extended by the Examiner during the personal interview on June 14, 2000.¹

The Declaration

In the Office Action, the Examiner objects to the failure to offer to surrender the original patent. An executed offer to surrender the patent is being obtained and will be provided to the Examiner as soon as it is available.

The Examiner also objects to the alleged failure to identify at least one error that is relied upon to support the reissue application. The Examiner rejects claims 1-26, 28-51, 53-72, 74-96, and 98-114 as being based on a defective reissue declaration.

A supplemental reissue declaration is being obtained and will be provided to the Examiner as soon as it is available. This declaration will remedy the alleged deficiencies noted by the Examiner.

Rejection Under 35 U.S.C. § 112

The Examiner rejects claims 29-35 and 75-81 under 35 U.S.C. § 112, ¶ 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. In particular, the Examiner correctly notes that claims 29-35 and 75-81 depended from canceled claims.

This Amendment corrects the dependency of the claims. Specifically, claims 29, 30, 33, and 34 have been amended to depend from claim 22, and claims 75, 76, 79, and 80 have been amended to depend from claim 68. Accordingly, the claims no longer depend upon canceled claims and now comply with 35 U.S.C. § 112, ¶ 2.

¹ It is noted for the record that although George Quillin authorized the interview, he did not attend.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejects claims 22-26, 28-51, 53-72, 74-96, and 98-114 as being unpatentable over a proposed combination of United States Patent No. 5,522,881 (“Lentz”) and United States Patent No. 3,974,526 (“Dardik”). The Examiner recognizes that Lentz does not teach the use of tissue in an assembly for insertion into a body passageway. The Examiner asserts, however, that Dardik teaches “utilizing tissue . . . for the purpose of reducing the need for additional operations.” The Examiner concludes that “[i]t would have been within the level of one skilled in the art at the time of the invention to have replaced the conduit of the Lentz device with the tissue taught by Dardik et al. in order to reduce the number of operations needed.”

Applicant respectfully traverses the rejection. Each of claims 22-26, 28-50, 68-72, and 74-95 recites an assembly for insertion into a body passageway including, *inter alia*, a tissue disposed adjacent to an interior surface of an expandable or deformable member. Each of claims 113 and 114 recites an assembly for insertion into a body passageway including, *inter alia*, a tissue configured to avoid exposure of an expandable or deformable stent to circulating body fluids when the assemble is inserted into the body passageway. Each of claims 51, 53-67, 96, 98-112 recites a method of preparing a graft prosthesis for insertion into a body passageway including, *inter alia*, the step of providing a tissue adjacent to an interior surface of an expandable or deformable member. Applicant respectfully submits that Lentz and Dardik do not render the claimed invention unpatentable for at least the reasons explained below.

The Examiner's Proposed Combination Would Not Work for Its Intended Use

One skilled in the art would not have combined Lentz and Dardik in the manner proposed by the Examiner. Specifically, one skilled in the art would not have made such a combination because it would not work for its intended use.

Lentz discloses an assembly having a tubular conduit 12 and two stents 28. The stents 28 are spaced from one another and are disposed at opposite ends of the conduit 12. Lentz lists a variety of materials that can be used to make the conduit 12. *See* col. 3, ll. 11-19. Notably, the lengthy list of materials includes only synthetic materials and does not include tissue.

Tissue is unsuitable for use as the conduit 12 in the Lentz assembly. See the attached Declaration of Zoltan G. Turi at ¶ 10. Tissue requires structural support greater than the support offered by the stents 28 of Lentz. *See* Turi Decl. at ¶ 8. If tissue were used as the conduit 12 in the Lentz assembly, the portion of the tissue between the two stents 28 would collapse, rendering the assembly unsuitable for its intended use.² *See* Turi Decl. at ¶¶ 8, 9.

Thus, even if Dardik taught the use of tissue as alleged by the Examiner, one of ordinary skill in the art would not have used such tissue in the Lentz assembly. Tissue is an unsuitable material for that use.

² In contrast, the synthetic materials disclosed in Lentz can be formed with sufficient rigidity to maintain a proper shape in the Lentz assembly. *See* Turi Decl. at ¶ 7.

There Is No Motivation to Combine

Additionally, there is no motivation to combine Lentz and Dardik in the manner suggested by the Examiner. The mere prior use of tissue as a graft material does not make it obvious to use tissue in the Lentz assembly.

The Federal Circuit has warned against the use of hindsight to combine conventional elements to achieve the claimed invention:

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."

Most if not all inventions arise from a combination of old elements. Thus, every element of a claimed invention may often be found in the prior art. However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant.

* * *

In this case, the Examiner and the Board fell into the hindsight trap. The idea of a single sensor controlling multiple valves, as opposed to multiple sensors controlling multiple valves, is a technologically simple concept. With this simple concept in mind, the Patent and Trademark Office found prior art statements that in the abstract appeared to suggest the claimed limitation. But, there was no finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of Kotzab's invention to make the combination in the manner claimed. [*In re Kotzab*, 217 F.3d 1365, 55 U.S.P.Q.2d 1313 (Fed. Cir. 2000) (emphasis added; citations omitted).]

Like *Kotzab*, the Examiner found a statement in the prior art that appeared to suggest the claimed limitation, but failed to show a specific understanding or principle that would have motivated one with no knowledge of Applicant's invention to make the claimed combination. For example, the Examiner asserts that Dardik teaches "utilizing tissue . . . for the purpose of reducing the need for additional operations." Dardik, however, merely discloses that using one type of tissue (umbilical cord veins) reduces the need for additional operations caused by another type of tissue (autogenous vein grafts). See col. 3, ll. 7-57. Dardik nowhere suggests that tissue should be substituted for synthetic materials such as those disclosed in Lentz. Thus, there is simply no motivation to combine Lentz and Dardik in the manner proposed by the Examiner.

Conclusion

As explained above, Dardik would not have suggested to one skilled in the art to use tissue in the Lentz assembly because tissue is unsuitable for such use and there is no motivation to combine Lentz and Dardik. For at least those reasons, the claimed invention is patentable over Lentz and Dardik.

In view of the foregoing, it is respectfully submitted that the pending claims are allowable. The Examiner is invited to telephone the undersigned if the undersigned can assist the Examiner or expedite prosecution of the application.

If Applicant has not accounted for any fees required by this Amendment, the Commissioner is hereby authorized to charge the missing fees to our Deposit Account No. 19-0741. If Applicant has not accounted for a required extension of time under 37 C.F.R.

§ 1.136, that extension is requested and the corresponding fee should be charged to our Deposit Account.

Respectfully submitted,

August 21, 2000

Date



Andrew E. Rawlins
Reg. No. 34,702

FOLEY & LARDNER
3000 K Street, N.W.
Suite 500
Washington, D. C. 20007-5109
(202) 672-5300